Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge** **Marianne B. Bowler**

DEY DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION *IN LIMINE* TO EXCLUDE FROM EVIDENCE THE REPORTS AND TESTIMONY OF STEPHEN W. SCHONDELMEYER

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") previously moved to exclude three categories of Dr. Schondelmeyer's reports and testimony:

> (i) that Dey was required to report, as AWP, the prices "generally and currently" paid in the market;
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> (ii) what Dey allegedly knew and intended; and
>
> (iii) what Medicare, Medicaid, and the 50 state Medicaid programs allegedly knew and intended.

At the hearing on May 3, 2010, this Court stated that the upcoming trial of this action will be limited to the government's Medicare claims. Thus, in addition to the grounds set forth above, those portions of Dr. Schondelmeyer's reports and testimony which relate to Medicaid reimbursement should now be excluded for the additional reason that they are irrelevant to the issues bring tried.

ARGUMENT

I. DR. SCHONDELMEYER'S OPINIONS ON MEDICAID REGULATIONS ARE IRRELEVANT

The only basis for Dr. Schondelmeyer's opinion that Dey was required to report "generally and currently" paid prices as AWP is his interpretation of the 1987 federal EAC regulation relating to Medicaid, 42 C.F.R. § 447.301. He cites no Medicare regulations, no scholarly research, and no published authorities to support that opinion. Moreover, Dr. Schondelmeyer's expertise is almost exclusively in the Medicaid context and his opinion on manufacturers' reporting obligations rest solely on a Medicaid regulation. Now that the upcoming trial concerns only Medicare reimbursement, Dr. Schondelmeyer's interpretation of federal Medicaid regulations, specifically 42 C.F.R. § 447.301, is irrelevant and his opinion that they require Dey to report "generally and currently" paid prices should be excluded for that reason alone. Dr. Schondelmeyer's opinions on how States were supposed to make Medicaid reimbursements is not relevant to the federal government's Medicare reimbursement program. Indeed, the government conceded that if the Medicare claims were bifurcated for trial, the scope of Dr. Schondelmeyer's testimony would be limited. (Opp. at 1, n.1.)[1] Thus, Dr. Schondelmeyer's reports and testimony should be excluded for the Medicare trial on this basis alone and resolution of the rest of Dey's motion should await a future trial on Medicaid.

II. LEGAL INTERPRETATION OF FEDERAL REGULATIONS IS IMPROPER

In addition to being irrelevant, Dr. Schondelmeyer's opinions on the meaning of federal Medicaid regulations is also improper. The government does not dispute that Dr. Schondelmeyer is not a lawyer and lacks expertise to interpret statutes, laws and regulations for

[1] References to "Opp." are to the pages of the Plaintiffs' Memorandum of Law in Opposition to Dey Defendants' Motion in Limine to Exclude From Evidence the Reports and Testimony of Stephen W. Schondelmeyer, dated April 21, 2010.

the jury "in a legal sense." (Tr. at 200:22-201:4.)[2] Indeed, "[e]xpert testimony proffered solely to establish the meaning of the law is presumptively improper." *U.S. v. Mikutowicz*, 365 F.3d 65, 73 (1st Cir. 2004) (citation omitted). Yet, Dr. Schondelmeyer repeatedly opines that Medicaid and Medicare require manufacturers, like Dey, to report drug prices that are "generally and currently paid by providers," and not list or undiscounted prices. This is a blatant legal conclusion, based solely on his (incorrect) interpretation of a single Medicaid regulation and a 1977 Medicaid directive.

The government attempts to support Dr. Schondelmeyer's opinions by characterizing them, not as legal opinions, but simply as "reference to the exact language of a regulation" (Opp. at 5) and an explanation of "the context and history of the regulations in question" (Opp. at 4). If all Dr. Schondelmeyer is doing, however, is quoting the exact language of a Medicaid regulation, then his testimony is not needed or useful. The Court can read the Medicaid regulations to the jury. Dr. Schondelmeyer would not be adding anything of value.

Of course, Dr. Schondelmeyer is not merely reading the "exact language" of the Medicaid EAC regulation. This is obvious because the Medicaid EAC regulation does not require manufacturers to report any specific price, "generally and currently paid" or otherwise, and does not define AWP. Rather, Dr. Schondelmeyer is purporting to offer his own legal interpretation of the Medicaid EAC regulation – exactly what the law forbids. Dr. Schondelmeyer opines repeatedly that Medicaid and Medicare "currently and historically have relied upon manufacturers' reporting of prices that do reflect the 'prices generally and currently paid by providers' in the marketplace." (Rep. at ¶ 80.)[3] Dr. Schondelmeyer also draws the legal

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[2] References to "Tr." are to the depositions of Dr. Schondelmeyer, dated February 25, 26, 27, May 21, and 22, 2009, attached as Exhibit A to the Declaration of Neil Merkl, previously filed on March 24, 2010.

[3] References to "Rep." are to the Expert Report of Dr. Schondelmeyer, dated January 22, 2009, attached as Exhibit B to the Declaration of Neil Merkl, previously filed on March 24, 2010.

conclusion that Dey's legal position in this lawsuit – that states favored using reported AWPs for policy reasons – "is not consistent with, and is in direct opposition to, long standing Medicaid statutes, regulations, policies, and practices." (Rep. at ¶ 158.)

The government now contends that Dr. Schondelmeyer is "fully aware that there was no outright requirement for any manufacturer to report AWPs to the government." (Opp. at 6.) Indeed, there is no such requirement; but Dr. Schondelmeyer opines at length that manufacturers were required to report drug prices that were "generally and currently paid" by providers and he relies on his interpretation of the Medicaid regulation to reach that legal conclusion. (Rep. at ¶¶ 52-53, 80.) Such testimony should be excluded.

The parties' disagreement, set forth in their briefs, over the meaning of the Medicaid EAC regulation itself establishes that Dr. Schondelmeyer's opinion is not a legitimate topic for expert testimony. (*See* Dey Br. at 6-8;[4] Opp. at 5-6.) The government argues that any such disagreement is not a basis for excluding Dr. Schondelmeyer's testimony. (Opp. at 5.) But, if his testimony is not excluded, then his cross-examination will be little more than a legal argument between Dr. Schondelmeyer and Dey's counsel over the proper legal interpretation of Medicaid regulations – exactly what the rule against the introduction of legal opinions through expert witnesses is meant to avoid. *See Mikutowicz*, 365 F.3d at 73.

The cases cited by the government actually support exclusion of Dr. Schondelmeyer's opinions. In *Powell v. Nunley*, No. CIV-08-0753-HE, 2010 U.S. Dist. LEXIS 26596, at *5-6 (W.D. Okla. Mar. 22, 2010), for example, the Court recognized the principle that "an expert's testimony not be permitted to define the legal parameters for the jury, so as to invade the

[4] References to "Dey Br." are to the pages of the Dey Defendants' Memorandum of Law in Support of Their Motion *in Limine* to Exclude from Evidence the Reports and Testimony of Stephen W. Schondelmeyer, previously filed on March 25, 2010.

province of the court." The Court allowed testimony by a criminal justice professor about standard police practices even though such practices were motivated, in part, by the need to comply with certain legal standards. Here, in contrast, Dr. Schondelmeyer has no training in the law and is not purporting to testify about standard practices in the Medicaid or Medicare industry; rather, he is testifying about the legal standards themselves and offering his legal interpretation of federal regulations. (Rep. at ¶¶ 54, 158.) Dr. Schondelmeyer also cites no scholarly works and no industry standards on the price reporting of manufacturers – nor can he. Dr. Schondelmeyer has previously conceded that he is "not aware of any" experts, other than himself, that have opined on the meaning of "generally and currently paid by providers" in the Medicaid EAC regulation and, in fact, "very few scholars have actually addressed this issue at all." (Calif. Tr. at 169:2-16; 174:19-175:21.)[5] Moreover, Dr. Schondelmeyer has admitted that "the regulation is what it is, and the way that will be interpreted is up to a judge and jury to evaluate." (Calif. Tr. at 170:2-10.) Thus, by his own admission, his legal opinion on the meaning of the Medicaid regulation should be left up to the judge and the jury when the Medicaid case is tried. Likewise, in *Flanagan v. Altria Group, Inc.*, 423 F. Supp. 2d 697, 700-702 (E.D. Mich. 2005), the Court approved of the rule that "[t]estimony should be excluded, however, where it amounts to a legal conclusion or merely tells the jury what result to reach" and only admitted the expert testimony in that case because it fell "short of legal conclusions."[6] Dr. Schondelmeyer repeatedly opines about the "specific legal requirements" of Medicaid

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[5] References to "Calif. Tr." are to the deposition of Dr. Schondelmeyer, dated September 15, 2009, in connection with the related action, *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., Inc. et al.*, attached as Exhibit 1 to the Reply Declaration of Neil Merkl, filed herewith.

[6] In *Reece v. Astrazeneca Pharmaceuticals, LP*, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007) and *Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598 (D. Minn. Feb.16, 2005), neither party raised the issue of whether the expert witness was offering an improper legal opinion and the Court did not address that issue in either case. Moreover, in *Lillebo*, the Court stated that "[the expert] will not be permitted to testify concerning the specific legal requirement of the FDCA and FDA regulations and whether or not [defendant's] actions comply with those requirements." 2005 WL 388598, at *5.

regulations, the "specific legal requirements" of drug manufacturers to report certain prices, and whether Dey's "actions comply with those requirements." This is exactly the type of testimony which should be excluded.

III. EXPERT OPINIONS ON KNOWLEDGE AND INTENT ARE IMPROPER

A. Dr. Schondelmeyer Conceded That His Testimony on Knowledge and Intent Would Not Assist the Jury

An expert's testimony is inadmissible if, as here, it usurps the role of the jury by interpreting evidence and telling the jury what result to reach. *See U.S. v. Zajanckauskas*, 441 F.3d 32, 39 (1st Cir. 2006) ("Expert testimony does not assist where the trier of fact has no need for an opinion because it easily can be derived from common sense . . . or simple logic."). The government does not dispute that Dr. Schondelmeyer is merely weighing the evidence. (Tr. at 199:11-200:4, 460:8-9; 461:4-5.) Nor does the government dispute that a jury will not need Dr. Schondelmeyer's help to understand or evaluate the evidence in this case – a fact conceded by Dr. Schondelmeyer himself. (Tr. at 462:17-22; 464:2-8.) The jury will be fully capable of hearing the evidence and determining what Dey knew or intended.

The government argues that Dr. Schondelmeyer's testimony is admissible because he is opining on a topic that is "complex and technical." (Opp. at 7.) This is wrong. Dr. Schondelmeyer has already admitted that "jurors certainly could understand everything" that he relied on in reaching his opinions – the government cannot now argue that those facts are somehow "complex and technical." (Tr. at 462:17-22.) Thus, by Dr. Schondelmeyer's own admission, this is not a case like *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 726 (E.D.N.C. 2007), in which "the facts surrounding the claims at issue are highly complex and technical" and expert testimony was necessary to assist the jury. *In re Diet Drugs Products Liability Litigation*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000), on the other

hand, is on point and was not distinguished by the government. As in that case, Dr. Schondelmeyer improperly seeks to usurp the role of the jury by interpreting selected factual evidence and telling them what result to reach.

In re Methyl Tertiary Butyl Ether Products Liability Litigation, 643 F. Supp. 2d 482 (S.D.N.Y. 2009), cited by the government, also supports exclusion of Dr. Schondelmeyer's testimony. There, the Court held that general testimony about the range of information available within a defendant's industry was permissible but that the testimony will be excluded if it "constitute[s] impermissible legal conclusions." *Id*. at 497.

B. Dr. Schondelmeyer's Opinions Lack a Reliable Foundation

Dey also established in its moving brief that Dr. Schondelmeyer's opinions on knowledge and intent were unreliable because they were based on a handful of Dey documents (out of several million) and other evidence cherry-picked by plaintiff's counsel. The government attempts to rebut this argument by citing to *United States v. Oussama Abdullah Kassir*, S2 04 Cr. 356 (JFK), 2009 U.S. Dist. LEXIS 28837, at *16-18 (S.D.N.Y. Apr. 2, 2009), claiming that the court in that case "rejected a challenge to the testimony [of an expert] based on accusations of cherry-picking of information and an inability to scientifically test the sufficiency of the information on which the conclusions were based." (Opp. 8-9.) This is a misleading characterization of *Oussama*. In that case, an expert on al Qaeda and other terrorist organizations was proffered in a criminal terrorism trial. *Oussama*, 2009 U.S. Dist. LEXIS 28837, at *2-5. The Court admitted his testimony, not in spite of cherry-picking of information, but because the expert did far more than review cherry-picked documents. *Id*. at *17-19. The *Oussama* court adopted the rationale of another court which had admitted the same expert's testimony:

> [Although] Kohlmann's methodology is not readily subject to testing and permits of no ready calculation of a concrete error rate, *it is more reliable than a simple cherrypicking of information* from websites and other sources. The testimony and evidence at the Daubert I hearing demonstrate that Kohlmann's opinions and conclusions are subjected to various forms of *peer review* and that the opinions he proposes to offer here regarding al Qaeda's origins, leaders and certain tradecraft are *generally accepted within the relevant community*. Kohlmann's methodology, as he describes it, is similar to that employed by experts that have been [permitted] to testify in other federal cases involving terrorist organizations.

Id. (emphasis added). In stark contrast, Dr. Schondelmeyer's opinions have not been subject to any peer review – nor can they. His opinions are based solely on a review of documents cherry-picked by counsel (documents, he admitted, any juror could read and understand). Thus, the *Oussama* case highlights the infirmities in Dr. Schondelmeyer's methodology and rationale and the unreliable foundation on which he bases his entire testimony about Dey's knowledge and intent.

Indeed, numerous courts have excluded or limited expert testimony because the methodology was unreliable. *See, e.g.*, *Crowley v. Chait*, 322 F. Supp. 2d 530, 542, 547 (D.N.J. 2004) (court concerned about "the perils of [an expert] relying on evidence hand-selected…by counsel"); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1086 (D. Kan. 2002) (in excluding expert's testimony, the court cited concerns about "the degree of [his] reliance on pre-selected evidence from interested parties"); *Roussell v. Brinker Int'l, Inc.*, No. H-05-3733, 2008 U.S. Dist. LEXIS 52568, at *102, *105 (S.D. Tex. July 9, 2008) (finding that expert's conclusions are less reliable when based on materials and individuals selected by counsel for review, expert did not know how the selections were made, and the small sample of data reviewed weighed against admissibility); *Lippe v. Bairnco Corp.*, 288 B.R. 678, 690-91, 697 (S.D.N.Y. 2003) (excluding testimony because, among other things, expert was unable to explain bases for opinion and relied on what counsel told her rather than conducting independent investigation).

The government also argues that it is Dey's obligation to point out information which Dr. Schondelmeyer failed to consider which would have changed his opinions. (Opp. at 9.) This is not the law, however, and the government does not cite a single authority for this proposition.[7] Indeed, it is the government's burden, as the party proffering Dr. Schondelmeyer's expert testimony, to establish that his methodology was reliable and they have not done so. In any case, he was asked whether he read through the deposition testimony of relevant Dey decision-makers and he could not answer. He also admitted that he reviewed less than twenty-five Dey documents out of 3.3 million. (Dey Br. at 12-15.) Among those he did review, is a "Reimbursement Comparison Worksheet" which he uses as the basis for his conclusion that Dey was marketing a spread on AWP to pharmacies. (Rep. at ¶¶ 93-98.) Yet this document does not concern reimbursement for Medicare, and therefore is not at issue in the upcoming trial; Medicare reimbursement is based on median AWP, and the Reimbursement Comparison Worksheets are irrelevant in that regard.

IV. DR. SCHONDELMEYER'S OPINION THAT DEY CAUSED MEDICARE TO PAY INFLATED PRICES SHOULD BE EXCLUDED

Dr. Schondelmeyer's opinions on what Medicare officials knew and did should also be excluded because he simply weighed evidence and made credibility determinations as to the contested factual issues in this case – whether Dey's actions caused Medicare to overpay. (Rep. ¶¶ 22, 80.) The government is a party to this action and it is intending to put on testimony about the operation of the Medicare reimbursement system and the knowledge of Medicare officials through several fact witnesses, including representatives from various DMERCs. *See* Dkt. 7103. These witnesses can be cross-examined about their personal knowledge. Allowing Dr.

[7] None of the cases cited by the government impose a burden on the party seeking to exclude expert testimony on the grounds that it is unreliable to come forward with evidence which would change the expert's opinions. (Opp. at 9.)

Schondelmeyer to opine as an expert on the knowledge and intent of the Medicare program effectively prevents cross-examination of the witnesses with personal knowledge of the facts. That is improper and should not be allowed.

The government argues that Dr. Schondelmeyer "does not testify with regard to legal causation" but "instead explains how reported and published prices are used in the operation of the Medicare and Medicaid programs." (Opp. at 10.) Specifically, "[i]n Medicare, he explains the J-code system and its use of median AWPs." (Opp. at 11.) But this is a distortion of Dr. Schondelmeyer's testimony – he seeks to tell the jury, not just how Medicare reimbursements work, but that Dey's actions caused Medicare to overpay. (Rep. at ¶¶ 101, 182-83, 212.) Thus, Dr. Schondelmeyer is seeking to testify as to legal causation, and it should not be allowed.

Moreover, Dr. Schondelmeyer's opinion on whether Dey caused Medicare to overpay is not based on any scholarly research or analysis. In fact, his opinion is admittedly speculative – he is opining on what "might have" happened if manufacturers had reported "accurate" prices. (Tr. at 159:16-160:7.) The extent of his speculation is apparent in his report:

> 182. The reporting of an inflated AWP for one or more NDCs within a J-code group by a drug company ***could lead*** to an inflated median for that J-code that would affect the payment amount for all manufacturers' drug products reimbursed under that J-code. If instead, a manufacturer reported a price, or AWP, based on actual sales to wholesalers or to direct purchasers, the published truthful AWP for each of the manufacturer's drug products ***may have*** resulted in a lower median price leading to lower payments.
>
> 183. A drug manufacturer's failure to report truthful prices ***may affect*** the reimbursement for all prescriptions paid based upon a J-code that includes one or more of that manufacturer's drug products, regardless of whose drug product was actually provided to the Medicare or Medicaid patient.

(Rep. at ¶ 182-83 (emphasis added).) Instead of disputing that this type of sheer speculation is groundless, the government now contends that Dr. Schondelmeyer "did not address hypothetical

changes that may have come about had some element of the [current reimbursement] system been different." (Opp. at 12.) Yet, that is exactly what Dr. Schondelmeyer is attempting to do in his report when he speculates that, had Dey reported "truthful" prices, Medicare payments "may have" been lower. Those portions of Dr. Schondelmeyer's testimony should, therefore, be excluded.

CONCLUSION

For the foregoing reasons, Dey respectfully requests that the Court enter an Order granting Dey's motion to exclude the reports and testimony of Dr. Stephen W. Schondelmeyer, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: June 24, 2010

Respectfully Submitted,
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 24, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Neil Merkl
Neil Merkl